K132010

510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirement of Safe Medical Devices Act of 1990 and 21 CFR 807.92.

VIDAS® *C. difficile* GDH

A. Submitter Information

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Date of Preparation:	May 2013

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B. Device Name

Trade Name:	VIDAS® *C. difficile* GDH
Common Name:	VIDAS *C. difficile* GDH Assay
Classification Name:	21 CFR 866.2660 – Microorganism Differentiation and Identification Device
	MCB – Antigen, *Clostridium difficile*

C. Predicate Device Name

Trade Name: C. DIFF QUIK CHEK® (TECHLAB, INC.), K053572

D. Device Description

The VIDAS® *C. difficile* GDH assay principle combines a two-step enzyme immunoassay sandwich method with a final fluorescent detection (ELFA).
The Solid Phase Receptacle (SPR®) serves as the solid phase as well as the pipetting device. Reagents for the assay are ready-to-use and are pre-dispensed in the sealed reagent strips. All of the assay steps are performed automatically by the instrument. The reaction medium is cycled in and out of the SPR several times. Each step is followed by a wash cycle which eliminates unbound components.

- Specific binding of GDH present in the sample with mouse monoclonal anti-GDH antibody coated on the interior of the SPR.
- Binding between GDH and mouse monoclonal anti-GDH antibody conjugated with alkaline phosphatase (ALP).
- Detection: alkaline phosphatase catalyzes the hydrolysis of the substrate (4-Methyl-umbelliferyl phosphate) into a fluorescent product (4-Methyl-umbelliferone) the fluorescence of which is measured at 450 nm.

The intensity of the fluorescence increases according to the quantity of GDH in the sample.

When the VIDAS *C. difficile* GDH test is completed, the results are analyzed automatically by the instrument, a test value is generated, and a result is printed for each sample.

E. Intended Use

VIDAS® *C. difficile* GDH (GDH) is an automated test based on the Enzyme Linked Fluorescent Assay technique (ELFA), for use on the VIDAS family instruments.
The VIDAS *C. difficile* GDH (glutamate dehydrogenase) assay is a qualitative test that detects the *C. difficile* antigen, glutamate dehydrogenase, as a screen for the presence of *C. difficile* in fecal specimens from persons suspected of having *C. difficile* infection (CDI). The test does not distinguish toxigenic from non-toxigenic strains of *C. difficile*. With the use of additional tests that detect *C. difficile* toxins, the test is to be used as an aid in the diagnosis of *C. difficile* infection. As with other *C. difficile* tests, results should be considered in conjunction with the patient history.

F. Technological Characteristics Summary

A general comparison of the similarities and differences of the assays is presented in the table below.

Item	VIDAS® *C. difficile* GDH Assay	C. DIFF QUIK CHEK® Assay (K053572)
Intended Use	VIDAS® *C. difficile* GDH (GDH) is an automated test based on the Enzyme Linked Fluorescent Assay technique (ELFA), for use on the VIDAS family instruments. The VIDAS *C. difficile* GDH (glutamate dehydrogenase) assay is a qualitative test that detects the *C. difficile* antigen, glutamate dehydrogenase, as a screen for the presence of *C. difficile* in fecal specimens from persons suspected of having *C. difficile* infection (CDI). The test does not distinguish toxigenic from non-toxigenic strains of *C. difficile*. With the use of additional tests that detect *C. difficile* toxins, the test is to be used as an aid in the diagnosis of *C. difficile* infection. As with other *C. difficile* tests, results should be considered in conjunction with the patient history.	The C. DIFF QUIK CHEK® test is a rapid membrane enzyme immunoassay for use as a screening test to detect *Clostridium difficile* antigen, glutamate dehydrogenase, in fecal specimens from persons suspected of having *C. difficile* disease. The test does not distinguish toxigenic from non toxigenic strains of *C. difficile*. With the use of additional tests that detect *C. difficile* toxins, the test is to be used as an aid in the diagnosis of *C. difficile* disease. As with other *C. difficile* tests, results should be considered in conjunction with the patient history.
Specimen	Fecal	Fecal
Analyte	*Clostridium difficile* glutamate dehydrogenase	*Clostridium difficile* glutamate dehydrogenase
Automated	Yes	No
Assay Technique	Enzyme-linked fluorescent assay (ELFA)	Rapid Membrane Enzyme immunoassay

All nonclinical and clinical tests were performed following the recommendations of the FDA draft guidance from November 29th 2010.

G. Nonclinical Tests

A summary of the non-clinical results is presented below.

Sample stability

Specimens storage after collection
Stool specimens may be stored at 2-8°C for 3 days (from time of collection) prior to processing. If longer storage is required, freeze the specimens at -70°C+/- 10°C up to one month. Avoid repeated freezing and thawing cycles and storage at -19/-31°C.

Specimens storage after pretreatment
Specimen supernatants may be stored up to 8 hours at 18-25°C or 48 hours at 2-8°C before being tested with the VIDAS *C. difficile* GDH assay. Specimen supernatants storage at -19/-31°C and -70°C +/-10°C was not validated and is therefore not recommended.

Precision

The within-laboratory precision was estimated at one site based on the recommendations of the CLSI® EP5-A2.
Three human samples, including 2 close to the clinical cut-off (1 high negative and 1 low positive) and 1 moderate positive, were tested in triplicate in 2 runs per day with 2 different operators, with 2 reagent lots for a total of 12 testing days (6 days of test per lot) on 1 VIDAS instrument (N=72 test values for each sample). Two calibrations were used for each reagent lot (3 days of test per calibration and lot) over the whole period of the study. Data from the study are summarized in the following table:

Sample	N	Mean test value	Repeatability		Total within-laboratory precision (total within-instrument, between-lot, between-calibration)	
			Standard deviation	CV (%)	Standard deviation	CV (%)
Sample 1 High negative	72	0.07	0.00	6.0	0.01	14.1
Sample 2 Low positive	72	0.12	0.01	5.2	0.01	11.9
Sample 3 Moderate positive	72	0.27	0.02	5.7	0.03	11.2

The within-laboratory precision of each panel member was also analyzed by determining the percentage of agreement between the test interpretation and the expected outcome (negative/positive interpretation). There was no change of interpretation for the 3 panel samples tested: all replicates of each panel member resulted in the expected interpretation. Data from the qualitative analysis are summarized in the following table:

Sample	Expected Result	N	Observed result Lot 1		Observed result Lot 2		Total Agreement	[CI_{95}] %
			Negative	Positive	Negative	Positive		
Sample 1 High negative	Negative	72	36	0	36	0	72/72 (100.0%)	[95.0 - 100.0]%
Sample 2 Low positive	Positive	72	0	36	0	36	72/72 (100.0%)	[95.0 - 100.0]%
Sample 3 Moderate positive	Positive	72	0	36	0	36	72/72 (100.0%)	[95.0 - 100.0]%

The reproducibility was estimated at three sites based on the recommendations of the CLSI® EP5-A2.
Three human samples, including 2 close to the clinical cut-off (1 high negative and 1 low positive) and 1 moderate positive, were tested in triplicate in 2 runs per day with 2 different operators, using 2 reagent lots for a total of 6 testing days (3 days of test for each lot) on 3 VIDAS instruments at 3 different sites (N=108 test values for each sample). One calibration was used for each reagent lot over the whole period of the study. Data from the study are summarized in the following table:

Sample	N	Mean test value	Reproducibility (total between sample preparation/operator/run/day/lot/ instrument)	
			Standard deviation	CV (%)
Sample 1 High negative	108	0.06	0.01	19.1
Sample 2 Low positive	108	0.12	0.02	12.9
Sample 3 Moderate positive	108	0.26	0.03	13.0

The reproducibility of each panel member was also analyzed by determining the percentage of agreement between the test interpretation and the expected outcome (negative/positive interpretation). Data from the qualitative analysis for all sites combined are summarized in the following table:

Panel Sample	Expected Result	N	Observed result Site 1		Observed result Site 2		Observed result Site 3		Total Agreement	[CI_{95}] %
			Negative	Positive	Negative	Positive	Negative	Positive		
Sample 1 High negative	Negative	108	36	0	36	0	35	1	107/108 (99.1%)	[94.9 - 99.9]%
Sample 2 Low positive	Positive	108	0	36	1	35	3	33	104/108 (96.3%)	[90.8 – 99.0]%
Sample 3 Moderate positive	Positive	108	0	36	0	36	0	36	108/108 (100.0%)	[96.6 – 100.0]%

Out of the 108 results obtained for each precision sample, there were:

- 1 change of interpretation (0.9%) for the high negative sample (Sample 1),
- 4 changes of interpretation (3.7%) for the low positive sample (Sample 2),
- 0 change of interpretation (0%) for the moderate positive sample (Sample 3).

The percentages of change of interpretation observed for Sample 1 and Sample 2 were less than 5%, which was considered as normal and expected for these types of samples very close to the assay decision threshold (average test value for Sample 1 = 0.06 and average test value for Sample 2 = 0.12 for a decision threshold at 0.10.

Strain reactivity

The VIDAS *C. difficile* GDH assay was evaluated using several strains of *C. difficile*. Strains were grown on Columbia agar + 5% sheep blood (bioMérieux ref. 43041).
The VIDAS *C. difficile* GDH detects the following *C.difficile* strains at the tested concentrations of $9x10^8$ CFU/mL (3 McFarland) and $3x10^6$ CFU/mL:

Toxinogenic *C.difficile* strains:		Non toxinogenic *C.difficile* strains:
ATCC® 43255™	ATCC® 43600™	ATCC® 700057™
ATCC® 9689™	ATCC® 43599™	ATCC® 43593™
ATCC® 700792™	ATCC® 43596™	X1a IS58
ATCC® 17858™	ATCC® 43594™	X1b R1 1402
ATCC® BAA–1805™	ATCC® 17857™	ATCC® 43601™ ($3x10^8$ CFU/mL only)
ATCC® BAA-1382™	ATCC® 43598™	
ATCC® 51695™	CCUG 20309	

The VIDAS *C. difficile* GDH detects the following *C.difficile* strains at the tested concentration of $9x10^8$ CFU/mL (3 McFarland):

Cardiff ECDC collection including the following ribotypes	001 (7 strains); 002; 003; 012; 014; 015; 017; 020; 023; 027; 029; 046; 053; 056; 070; 075; 077; 078; 081; 087; 095; 106; 126; 131; VPI 10463; 005; 010; 045; 048; 156; 174.
bioMerieux collection including the following ribotypes	001 (6 strains); 002 (9 strains); 005 (2 strains); 010 (1 strain); 012 (4 strains); 014 (10 strains); 015 (1 strain); 017 (20 strains); 020 (5 strains); 023 (1 strain); 027 (24 strains); 047 (1 strain); 050 (1 strain); 053 (4 strains); 054 (2 strains); 056 (2 strains); 057 (1 strain); 058 (1 strain); 075 (1 strain); 078 (3 strains); 096 (1 strain); 097 (1 strain); 103 (2 strains); 106 (16 strains); 110 (2 strains); 118 (1 strain); 153 (1 strain); 177 (1 strain).

Analytical sensitivity

Limit of detection

The limit of detection was evaluated using a range of dilutions of purified native *C.difficile* GDH and recombinant *C. difficile* GDH in a pool of C. *difficile*-negative stool samples based on the recommendations of the CLSI EP17-A.
The limit of detection of the VIDAS *C. difficile* GDH assay (95% detection rate for positive samples) is **3.0 ng/mL** for **purified native GDH**.

Hook effect

No hook effect was observed up to **purified native GDH** concentrations of **2 µg/Ml**.

Interferences

Study of drug interferences and other potentially interfering substances

Potential interferences by commonly used drugs and other substances was determined based on the recommendations of the CLSI® EP7-A2, at 2 levels of GDH (a low positive close to the clinical cut-off and a high positive).

Tested compound	Highest concentration tested	Result
Hemoglobin	3.2 mg/mL	No significant interference observed
Lipids	20 mg/mL	No significant interference observed
Mucin	3.33 mg/mL	No significant interference observed
Amoxicillin	206 µmol/L	No significant interference observed
Bismuth salicylate	8.2 mg/mL	No significant interference observed
Calcium carbonate	13.06 mg/mL	Potential interference*
Ceftriaxone	1.46 mmol/L	No significant interference observed
Benzalkonium chloride	2 µg/mL	No significant interference observed
Ciprofloxacin	30.2 µmol/L	No significant interference observed
Erythromycin	81.6 µmol/L	No significant interference observed
Ethanol	86.8 mmol/L	No significant interference observed
Fidaxomicin	4 mg/mL	No significant interference observed
Gentamicin	21 µmol/L	No significant interference observed
Mineral oil	0.27 v/v	Potential interference*
Hydrocortisone	0.6 mg/mL	No significant interference observed
Aluminium hydroxide	15.3 mg/mL	No significant interference observed
Magnesium hydroxide	6.2 mg/mL	No significant interference observed
Lidocaine	0.12 mg/mL	No significant interference observed
Loperamide	0.08 mg/mL	No significant interference observed
Mesalazine	19.2 mg/mL	No significant interference observed
Metronidazole	2 mg/mL	No significant interference observed
Naproxen	2170 µmol/L	No significant interference observed
Nystatin	600 UI/mL	No significant interference observed
Phenylephrine	0.225 mg/mL	No significant interference observed
Sennosides	0.24 mg/mL	No significant interference observed
Tergitol (nonoxynol-9)	0.5 v/v	Potential interference*
Tetracycline	34 µmol/L	No significant interference observed
Vancomycin	5 mg/mL	No significant interference observed

*Calcium carbonate at 9.80 mg/mL, Mineral oil at 0.20 v/v and Tergitol at 0.125 v/v did not cause interference.

Cross-reactivity and microbial interference:

To test for cross-reactivity, each micro-organism was diluted in a pool of *C. difficile*-negative stool samples, pretreated and a single replicate was tested using the VIDAS *C. difficile* GDH assay.
To test for microbial interference, each micro-organism was diluted in a pool of *C. difficile*-positive stool samples, pretreated and a single replicate was tested using the VIDAS *C. difficile* GDH assay.
For both cross-reactivity and microbial interference studies, the micro-organisms were tested at a concentration of $3x10^8$ CFU/mL (1 McFarland) for bacteria and $1x10^5$ PFU/mL for viruses.
None of the following micro-organisms, present in the stool samples, reacted with the VIDAS *C. difficile* GDH assay:

Abiotrophia defectiva, Acinetobacter baumannii, Acinetobacter lwoffii, Aeromonas hydrophila ssp hydrophila, Alcaligenes faecalis ssp faecalis, Anaerococcus tetradius, Bacillus cereus, Bacteroides caccae, Bacteroides merdae, Bacteroides stercoris, Bifidobacterium adolescentis, Bifidobacterium longum, Campylobacter jejuni ssp jejuni, Candida albicans, Candida catenulata, Cedecea davisae, Chlamydia trachomatis, Citrobacter amalonaticus, Citrobacter freundii, Citrobacter koseri, Citrobacter sedlakii, Clostridiuim nexile, Clostridium beijerinckii, Clostridium bifermentans, Clostridium bolteae, Clostridium butyricum, Clostridium chauvoei, Clostridium fallax, Clostridium haemolyticum, Clostridium histolyticum, Clostridium innocuum, Clostridium novyi, Clostridium paraputrificum, Clostridium perfringens, Clostridium ramosum, Clostridium scindens, Clostridium septicum, Clostridium sordellii, Clostridium sphenoides, Clostridium spiroforme, Clostridium sporogenes, Clostridium symbosum, Clostridium tertium, Clostridium tetani, Collinsella aerofaciens, Corynebacterium genitalium, Desulfovibrio piger, Edwardsiella tarda, Eggerthella lenta, Enterobacter aerogenes, Enterobacter cloacae, Enterococcus casseliflavus, Enterococcus cecorum, Enterococcus dispar, Enterococcus faecalis, Enterococcus faecium, Enterococcus gallinarum, Enterococcus hirae, Enterococcus raffinosus, Escherichia coli, Escherichia fergusonii, Escherichia hermannii, Flavonifractor plautii, Fusobacterium varium, Gardnerella vaginalis, Gemella morbillorum, Hafnia alvei, Helicobacter fenneliae, Helicobacter pylori, Klebsiella oxytoca, Klebsiella pneumoniae ssp pneumoniae, Lactobacillus acidophilus, Lactobacillus reuteri, Lactococcus lactis ssp lactis, Leminorella grimontii, Listeria grayi, Listeria innocua, Listeria monocytogenes, Peptoniphilus asaccharolyticus, Peptostreptococcus anaerobius, Plesiomonas shigelloides, Porphyromonas asaccharolytica, Prevotella melaninogenica, Proteus mirabilis, Proteus penneri, Providencia alcalifaciens, Providencia rettgeri, Providencia stuartii, Pseudomonas aeruginosa, Pseudomonas putida, Salmonella enterica ssp arizonae, Salmonella ser.Choleraesuis, Salmonella ser.Typhimurium Serratia liquefaciens, Serratia marcescens, Shigella boydii, Shigella dysenteriae, Shigella sonnei, Staphylococcus aureus ssp aureus, Staphylococcus epidermidis, Stenotrophomonas maltophilia, Streptococcus agalactiae, Streptococcus dysgalactiae ssp dysgalactiae,Streptococcus intermedius, Streptococcus uberis, Trabulsiella guamensis, Veillonella parvula, Vibrio cholerae, Vibrio parahaemolyticus,Yersinia bercovieri, Yersinia rohdei, Adenovirus 40 et 41, Rotavirus RF, Norovirus, Enterovirus 70, Echovirus 12, Coxsackie virus, Cytomegalovirus AD169.

H. Clinical Testing

Clinical sensitivity and specificity

1904 (1891 prospective and 13 retrospective) stool samples collected from patients suspected of having *C. difficile* infection (CDI) were tested at three sites (USA and Europe). The age groups of the patients range from 1 year to 100 years. A single replicate of each sample was tested using VIDAS *C. difficile* GDH on a VIDAS instrument. A bacterial culture test was performed for each sample on a CCFA medium according to the instructions for use.Data from the study are summarized in the following tables:

Performance of the VIDAS *C. difficile* GDH assay versus CCFA bacterial culture on prospective samples

		CCFA bacterial culture test							
		Site 1 (EU)		Site 2 (US)		Site 3 (US)		Total (All Sites)	
		Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative
VIDAS *C. difficile* GDH	Positive	42	24	78	21	163	113	283	158*
	Negative	7	451	4	363	2	623	13**	1437
Total		49	475	82	384	165	736	296	1595
Performance		%	**[$CI_{95\%}$]**	%	**[$CI_{95\%}$]**	%	**[$CI_{95\%}$]**	%	**[$CI_{95\%}$]**
Sensitivity		85.7%	[72.8 - 94.1]%	95.1%	[88.0 - 98.7]%	98.8%	[95.7 - 99.9]%	95.6%	[92.6 - 97.6]%
Specificity		94.9%	[92.6 - 96.7]%	94.5%	[91.8 - 96.6]%	84.6%	[81.8 - 87.2]%	90.1%	[88.5 - 91.5]%
Negative Predictive Value (NPV)		98.5%	[96.9 - 99.4]%	98.9%	[97.2 - 99.7]%	99.7%	[98.8 - 99.9]%	99.1%	[98.5 - 99.5]%

* 158 samples were found positive with the VIDAS *C. difficile* GDH assay and negative with the CCFA bacterial culture test, 73 of which were found positive and 85 negative with the commercially available *C. difficile* GDH assay.
** 13 samples were found negative with the VIDAS *C. difficile* GDH assay and positive with the CCFA bacterial culture test, 9 of which were found negative and 4 positive with the commercially available *C. difficile* GDH assay.
Out of 2038 patient samples tested with the VIDAS *C. difficile* GDH assay, 21 (1.0%) were reported as invalid.

Testing on retrospective samples
Thirteen (13) retrospectively collected samples from pediatric patients submitted for routine *C. difficile* testing (2-12 years) were assayed for *C. difficile* according to the same protocol. For these 13 retrospective samples alone, the VIDAS *C. difficile* GDH assay demonstrated a sensitivity of 100.0% (10/10) and a specificity of 33.3% (1/3).

Performance of the VIDAS *C. difficile* GDH assay versus CCFA bacterial culture on all prospective and retrospective samples
For all 1904 specimens and all sites combined, the VIDAS *C. difficile* GDH assay demonstrated a sensitivity of 95.8% (293/306) with 95%CI: 92.8 – 97.7%, a specificity of 90.0% (1438/1598) with 95%CI: 88.4 – 91.4%, and a negative predictive value of 99.1% with 95%CI: 98.5 – 99.5%.

Sensitivity and Specificity performances versus CCFA medium by age group on prospective samples

Age Group	VIDAS Positive /CCFA Positive	Sensitivity [CI_{95}] %	VIDAS Negative /CCFA Negative	Specificity [CI_{95}] %
< 2 years	1/1	100.0% [2.5 – 100.0]%	2/2	100.0% [15.8 - 100.0]%
2-12 years	12/12	100.0% [73.5 - 100.0]%	39/44	88.6% [75.4 - 96.2]%
13-21 years	13/13	100.0% [75.3 - 100.0]%	40/45	88.9% [75.9 - 96.3]%
22-59 years	122/125	97.6% [93.1 - 99.5]%	562/632	88.9% [86.2 - 91.3]%
≥ 60 years	135/145	93.1% [87.7 - 96.6]%	794/872	91.1% [89.0 - 92.9]%

For all 69 (56 prospective and 13 retrospective) samples from the 2-12 years pediatric population, the VIDAS *C. difficile* GDH assay demonstrated a sensitivity of 100.0% (22/22) with 95%CI: 84.6 – 100.0%, and a specificity 85.1% (40/47) with 95%CI: 71.7 – 93.8%.

Method comparison with a commercially available *C. difficile* GDH assay

1904 (1891 prospective and 13 retrospective) stool samples collected from patients suspected of having *C. difficile* infection (CDI) were tested at 3 sites (USA and Europe). A single replicate of each sample was tested using VIDAS *C. difficile* GDH on a VIDAS instrument and a commercially available *C. difficile* GDH assay.
Data from the study are summarized in the following table:

Method comparison between the VIDAS *C. difficile* GDH assay and the commercially available *C. difficile* GDH assay on prospective samples

		Commercially available *C. difficile* GDH assay							
		Site 1 (EU)		Site 2 (US)		Site 3 (US)		Total (All Sites)	
		Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative
VIDAS *C. difficile* GDH	Positive	56	10	92	7	207	69	355	86
	Negative	4	454	2	365	4	621	10	1440
Total		60	464	94	372	211	690	365	1526
Performance		%	[$CI_{95\%}$]	%	[$CI_{95\%}$]	%	[$CI_{95\%}$]	%	[$CI_{95\%}$]
Positive Percent Agreement		93.3%	[83.8 – 98.2]%	97.9%	[92.5 – 99.7]%	98.1%	[95.2 – 99.5]%	97.3%	[95.0 – 98.7]%
Negative Percent Agreement		97.8%	[96.1 – 99.0]%	98.1%	[96.2 – 99.2]%	90.0%	[87.5 – 92.1]%	94.4%	[93.1 – 95.5]%

In order to better estimate the performance of the VIDAS *C. difficile* GDH assay in specimens from pediatric patients (2-12 years), thirteen (13) *C. difficile* retrospectively collected samples were tested according to the same protocol.For all 1904 specimens and all sites combined, the VIDAS C. difficile GDH assay demonstrated a positive percent agreement of 97.3%

(367/377) with 95%CI: 95.2 – 98.7%, and a negative percent agreement of 94.4% (1441/1527) with 95%CI: 93.1 – 95.5%.

Method comparison with bacterial culture (*C. difficile* chromogenic medium)

1904 (1891 prospective and 13 retrospective) stool samples collected from patients suspected of having *C. difficile* infection (CDI) were tested at 3 sites (USA and Europe). A single replicate of each sample was tested using VIDAS *C. difficile* GDH on a VIDAS instrument. A bacterial culture test was performed for each sample on a *C. difficile* chromogenic medium according to the instructions for use.
Data from the study are summarized in the following table:

Performance of the VIDAS *C. difficile* GDH assay versus *C. difficile* chromogenic media bacterial culture on prospective samples

		***C. difficile* chromogenic bacterial culture test**							
		Site 1 (EU)		Site 2 (US)		Site 3 (US)		Total (All Sites)	
		Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative
VIDAS *C. difficile* GDH	Positive	42	24	85	14	187	89	314	127
	Negative	8	450	3	364	14	611	25	1425
Total		50	474	88	378	201	700	339	1552
Performance		%	**[$CI_{95\%}$]**	%	**[$CI_{95\%}$]**	%	**[$CI_{95\%}$]**	%	**[$CI_{95\%}$]**
Positive Percent Agreement		84.0	[70.9 - 92.8]%	96.6%	[90.4 - 99.3]%	93.0%	[88.6 - 96.1]%	92.6%	[89.3 - 95.2]%
Negative Percent Agreement		94.9%	[92.6 - 96.7]%	96.3%	[93.9 – 98.0]%	87.3%	[84.6 - 89.7]%	91.8%	[90.3 - 93.1]%

In order to better estimate the performance of the VIDAS *C. difficile* GDH assay in specimens from pediatric patients (2-12 years), thirteen (13) *C. difficile* retrospectively collected samples were tested according to the same protocol.For all 1904 specimens and all sites combined, the VIDAS *C. difficile* GDH assay demonstrated a positive percent agreement of 92.9% (325/350) with 95%CI: 89.6 – 95.3%, and a negative percent agreement of 91.8% (1426/1554) with 95%CI: 90.3 – 93.1%.

I. Conclusion

The results from the non-clinical and clinical studies submitted in this premarket notification are complete and demonstrate that the VIDAS® *C. difficile* GDH assay is substantially equivalent to the predicate device identified in Item C of this summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Center – WO66-G609
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October 9, 2013

Re: K132010
Trade/Device Name: VIDAS *C. difficile* GDH
Regulation Number: 21 CFR § 866.2660
Regulation Name: Microorganism Differentiation and Identification Device
Regulatory Class: I
Product Code: MCB
Dated: September 16, 2013
Received: September 17, 2013

Dear Ms. Koch-Mathian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sally A. Hojvat -S

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):__K132010_____

Device Name: VIDAS® *C. difficile* GDH

Indications For Use:

VIDAS® *C. difficile* GDH (GDH) is an automated test based on the Enzyme linked Fluorescent Assay technique (ELFA), for use on the VIDAS family instruments.
The VIDAS *C. difficile* GDH *(*glutamate dehydrogenase*)* assay is a qualitative test that detects the *C. difficile* antigen, glutamate dehydrogenase, as a screen for the presence of *C. difficile* in fecal specimens from persons suspected of having *C. difficile* infection (CDI). The test does not distinguish toxigenic from non-toxigenic strains of *C. difficile*. With the use of additional tests that detect *C. difficile* toxins, the test is to be used as an aid in the diagnosis of *C. difficile* infection. As with other *C. difficile* tests, results should be considered in conjunction with the patient history.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Ribhi Shawar -S
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